SHRI BIREN SINGH ENGTI: Sir, as I said earlier in my statement, in the Seventh Five Year Plan, we have a total of Rs. 163 crores for the States and the Union Territories. All the Staet Governments and the Union Territories have their component in their State Plan regarding the research and development. They are doing it. (*Interruption*)

MR. CHAIRMAN: He is referring about the backward States.

SHRI BIREN SINGH ENGTI: All the States, Sir.

श्री कैलाश पति मिश्र : सभापति जी, मुझे उत्तर प्राप्त नहीं हुआ है ।

श्री सभापति : आपके प्रश्न का उन्होंने उत्तर दिया है कि प्रयास कर रहे है ।

श्री कैलाश पति मिश्र : महोदय, रिप्लाई नहीं आया है । राज्यों मे जो अन्तर आ गया है वह आगे बढ़े हुए राज्यों मे कुछ राज्य बहुत पीछे छूट गये हैं (**व्यवधान**)

श्री चतुरानन मिश्र : वो बैकवर्ड स्टेट्स को उठाने के लिये प्रयास कर रहे है और यह उत्तर के लिये प्रयास कर रहे हैं ।

SHRI MADHAVSINH SOLANKI: Sir, efforts are made to deevlop science and technology in all States and most of the States have already established their departments of science and technology. Where the States are backward and need help, the Government would surely consider.

Drugs cleared for marketing

*244. DR. (SHRIMATI) SAROJINI MAHISHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the names of the drugs cleared for marketing in the country from 1st January to 31st October, 1988;

(b) what were the forms of formulations and strengths under which these were allowed;

(c) what were the indications for which each drug had been allowed for marketing;

(d) what were the contra-indications of each and what precautions had been suggested;

(e) whether it is a fact that package insert is not provided along with the medicines; and

(f) if so, what action had been taken in this regard?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (d) The names of drugs approved for marketing under Rule 30A of the Drugs and Cosmetics Rules for the period from 1st January, 1988 to 31st October, 1988 along with other required informtaion are at Annexure. (*See* Appendix CXLVIII, Annexure No. 93) and Statement (*See* below.)

(e) and (f) While leading manufacturers generally give package inserts, there is no specific provision in the Drugs and Cosmetics Rules for such inserts. However, all prescription medicines carry a warning on label and cartons that the medicines are required to be sold on the prescription of a Registered Medical Practitioner only.

Statement

Sl. No	Name of the drug	Contra-indications/precautions to be observed
1	2	3
1	Etoposide Caps/Inj	To be administered only in life threatening condition. Contra-indicated in acute infections. Blood count to be monitored. Contra-indicated in pregnant women
2	Bezafibrate Tabs.	Drug to be withdrawn if not tolerated.
3	Amineptine Tabs.	To be used with caution in patients with impaired liver function and other organic diseases.
4	Astemaole Tabs.	Avoid administration along with C.N.S. depresents.
5	Budesonide Inhaler	To avoid administration in non-steroid dependent asthma.
6	Penfluridol Tabs.	Caution in patients under the influence of C.N.S. depresents and in patients with bone marrow depression.
7	Aclarubicin Inj.	Contra-indicated in acute infections. Blood count to be monitored. Contra-indicated in pregnant women.
8	Zidovidine Caps.	Care should be taken in patients suffering from organic disease.
9	Ceftriazone Sodium injection	Administer with great care in patients allergic to penicillin.
10	Minoxidil Topical Lotion	Minoxidil is contra-indicated in phaeochromocytoma.
11	Benzydamine Topical cream	No special contra-indication.
12	Interferon alpha 28 injection	Contra-indicated in bone marrow insufficiency.
13	Melagenina Lotion	No special contra-indication.
14	Amrinone Inj.	To be withdrawn if not tolerated. Guard against thrambocytopenia and fever.
15	Ethamsylate Tabs.	High molecular plasma expanders should not be given before ethamoylate.
16	Minocycline Tabs./Caps./Oral/Sus.	Reduce dose if there is history of renal impairment.
17	Alprozolam Tabs.	Have dependence potential.
18	Cefuroxime Inj.	Administer with great care in patients allergic to penicillins.
19	Tertatotol Hcl Tabs.	It should be avoided if there is metabolic disease.

1	2	3
20	Cyclosporin Oral solution/Inj./Caps.	Contra-indicated in bone marrow depression and acute infection.
21	Ceftazidime Pentahydrate Inj.	Administer with great care in petients allergic to pencilline.
22	Gemfibrozil Caps.	Drug to be withdrawn if not tolerated.
23	Trichabendazol (Vet.) Bolus & Suspension.	Contra-indicated in pregnancy.

DR. (SHRIMATI) SAROJINI MAHISHI: Sir, the Minister has said that there is no specific mention in rule 33 of the Drugs and Cosmetics Rules that there should be special mention of the side-effects, the harmful effects, the contra-indications, the Precautionary measures, etc, but, however, the Registered Medical Practitioners will take all these into consideration. Sir, there are many drugs which have been banned by other countries. For example, even Analgyn, the brand name of which is Novalgyn, which is banned by more than 70 countries is being sold in India as one of the common drugs. There are also other drugs like Oxycanal Butazone and Cynyl Butazone which are very harmful. If a person who is addicted to drinking takes certain traquillizers, the next day he will not be in this world. Therefore, I would like to mention that the package inserts should consist of these things also and along with indications, ingredients, date of expiry, etc., these things should also be made compulsory under rule 33. Precautionary measures contra-indications and harmful effects of drugs also should be mentioned. There are many people who resort to self-medication Therefore, I would like to know whether the Government is going to take it seriously and make it part of rule 33-J that it should be mentioned necessarily and be part of the package instrt. (*Interruptions*)

KUMARI SAROJ KHAPARDE: Whatever suggestions have been given by the hon. Member are really welcome by the Government and by all of us. I would like to mention here the difficulties in inserting the information on all drugs. Firstly, there is no provision in the Drugs and Cosmetics Act and the Rules to compel a drug manufacturer to give the package insert. Secondly, (*Interruptions*)...in our country, all the information given in the package insert is difficult to be printed on a small label or strip. Thirdly, insertion of the package insert may increase the cost of the medicine, particularly in India, when such... (*Interruptions*)

MR. CHAIRMAN: Please, let her reply.

(*Interruptions*)

KUMARI SAROJ KHAPARDE: Sir, these are the difficulties in inserting all these things in a package in a carton. However, the suggestions given by hon. Members in this regard are welcome and will be taken care of. We will try to implement any suggestion that is possible of implementation.

MR. CHAIRMAN: Question Hour is over.